

# IN THE CLAIMS:

Please amend the claims to have the status and content indicated in the following listing of claims, wherein any cancellation of claims is made *without prejudice*.

1. (Currently amended) A lyophilized composition comprising a physiologically active substance and a stabilizer, wherein the stabilizer is a recombinant or synthetic gelatin-like polypeptide having a molecular weight between 3,000 Dalton and 80,000 Dalton and comprising at least one stretch of 10 or more consecutive repeats of Gly-Xaa-Yaa triplets, wherein each of Xaa and Yaa is an amino acid, wherein at least 20% of the amino acids in the recombinant or synthetic polypeptide are present in the form of consecutive Gly-Xaa-Yaa triplets and wherein the recombinant or synthetic polypeptide has a calculated glass transition temperature of higher than 180 degrees Celsius as calculated using formula 8 and 9 in Y. Matveev et al. Food Hydrocolloids Vol. 11 no. 2, pp. 125-133, 1997. the following equations (8) and (9)

$$(8) \ T_g^{-1} = \sum_{i=1}^{20} \phi_i T_{g,i}^{-1} \quad \text{wherein} \quad (9) \ \phi_i = n_i \Delta V_i / \sum_{i=1}^{20} n_i \Delta V_i$$

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wherein  $T_g$  is the glass transition temperature of the polypeptide,  $\Delta V_i$  is the van der Waals volume of the  $i$ th amino acid residue,  $n_i$  is the number of amino acid residues of  $i$ th type per mole of polypeptide,  $T_{g,i}$  is the partial increment of the  $T_g$  and the summations  $i=1$  to 20 are the summations of the values for the partial values of  $T_g$  and  $\Delta V$  of the separate amino acids as follows:

No.	Amino Acid	T <sub>g,i</sub> (Kelvin)	$\Delta V_i$
1	Gly	599	47.3
2	Ala	621	64.4
3	Val	931	98.6
4	Leu	400	115.7
5	Ile	400	115.7
6	Phe	528	139.9
7	Pro	423	88.0
8	Trp	544	196.9
9	Ser	311	66.1
10	Thr	321	88.9
11	Met	362	120.6
12	Asn	232	94.6
13	Gln	312	111.7
14	Cys-sh	418	82.2
15	Asp	672	80.1
16	Glu	487	97.2
17	Tyr	573	136.9
18	His	488	118.9
19	Lys	258	118.1
20	Arg	410	138.4

2. (Cancelled)
3. (Previously presented) A composition as in claim 1 wherein said recombinant or synthetic gelatin-like polypeptide has a molecular weight between 3,000 Dalton and 15,000 Dalton.

4. (Previously presented) A composition as in claim 1 wherein the glass transition temperature of the recombinant or synthetic gelatin-like polypeptide is higher than 190 degrees Celsius.
5. (Previously presented) A composition as in claim 1 wherein the recombinant or synthetic gelatin-like polypeptide has a bimodal molecular weight distribution.
6. (Previously presented) A composition as in claim 1 wherein the recombinant or synthetic gelatin-like polypeptide is free from helical structure.
7. (Previously presented) A composition as in claim 1 wherein the number of hydroxyproline residues in the recombinant or synthetic gelatin-like polypeptide is less than 5% of the total number of amino acid residues.
8. (Canceled)
9. (Currently amended) Process for lyophilizing a composition, the process comprising lyophilizing a composition comprising a physiological active substance and a stabilizer wherein the stabilizer ~~is~~ comprises a recombinant or synthetic gelatin-like polypeptide comprising a molecular weight between 3,000 Dalton and 80,000 Dalton at least one stretch of 10 or more consecutive repeats of Gly-Xaa-Yaa triplets, wherein each of Xaa and Yaa is an amino acid, wherein at least 20% of the amino acids are present in the form of consecutive Gly-Xaa-Yaa triplets and less than 5% of the total number of amino acid residues are hydroxyproline residues and wherein said recombinant or synthetic gelatin-like polypeptide has a calculated glass transition temperature of higher than 180 degrees Celsius as calculated using the following formulae (8) and (9)

$$(8) T_g^{-1} = \sum_{i=1}^{20} \phi_i T_{g,i}^{-1} \quad \text{wherein} \quad (9) \quad \phi_i = n_i \Delta V_i / \sum_{i=1}^{20} n_i \Delta V_i$$


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wherein  $T_g$  is the glass transition temperature of the polypeptide,  $\Delta V_i$  is the van der Waals volume of the  $i$ th amino acid residue,  $n_i$  is the number of amino acid residues of  $i$ th type per mole of polypeptide,  $T_{g,i}$  is the partial increment of the  $T_g$  and the summations  $i=1$  to 20 are the summations of the values for the partial values of  $T_g$  and  $\Delta V$  of the separate amino acids as follows:

No.	Amino Acid	$T_{g,i}$ (Kelvin)	$\Delta V_i$
1	Gly	599	47.3
2	Ala	621	64.4
3	Val	931	98.6
4	Leu	400	115.7
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6	Phe	528	139.9
7	Pro	423	88.0
8	Trp	544	196.9
9	Ser	311	66.1
10	Thr	321	88.9
11	Met	362	120.6
12	Asn	232	94.6
13	Gln	312	111.7
14	Cys-SH	418	82.2
15	Asp	672	80.1
16	Glu	487	97.2
17	Tyr	573	136.9
18	His	488	118.9
19	Lys	258	118.1
20	Arg	410	138.4

10. (Currently amended) A composition as in claim ~~2~~ 1 wherein the glass transition temperature of the recombinant or synthetic gelatin-like polypeptide is higher than 190 degrees Celsius.
11. (Previously presented) A composition as in claim 3 wherein the glass transition temperature of the recombinant or synthetic gelatin-like polypeptide is higher than 190 degrees Celsius.
12. (Currently amended) A composition as in claim ~~2~~ 1 wherein the recombinant or synthetic gelatin-like polypeptide has a bimodal molecular weight distribution.
13. (Previously presented) A composition as in claim 3 wherein the recombinant or synthetic gelatin-like polypeptide has a bimodal molecular weight distribution.
14. (Previously presented) A composition as in claim 4 wherein the recombinant or synthetic gelatin-like polypeptide has a bimodal molecular weight distribution.
15. (Currently amended) A composition as in claim ~~2~~ 1 wherein the recombinant or synthetic gelatin-like polypeptide is free from helical structure.
16. (Previously presented) A composition as in claim 3 wherein the recombinant or synthetic gelatin-like polypeptide is free from helical structure.
17. (Previously presented) A composition as in claim 4 wherein the recombinant or synthetic gelatin-like polypeptide is free from helical structure.
18. (Previously presented) A composition as in claim 5 wherein the recombinant or synthetic gelatin-like polypeptide is free from helical structure.

19. (Currently amended) A composition as in claim 2 1 wherein the number of hydroxyproline residues in the recombinant or synthetic gelatin-like polypeptide is less than 5% of the total number of amino acid residues.

20. (Previously presented) A composition as in claim 3 wherein the number of hydroxyproline residues in the recombinant or synthetic gelatin-like polypeptide is less than 5% of the total number of amino acid residues.

21. (Currently amended) A composition as in claim 2 1 wherein the glass transition temperature of the recombinant or synthetic gelatin-like polypeptide is higher than 200 degrees Celsius.

22. (Previously presented) A composition as in claim 2 wherein the glass transition temperature of the recombinant or synthetic gelatin-like polypeptide is higher than 200 degrees Celsius.

23. (Previously presented) A composition as in claim 3 wherein the glass transition temperature of the recombinant or synthetic gelatin-like polypeptide is higher than 200 degrees Celsius.

24. (Currently amended) A composition as in claim 2 1 wherein the complete amino acid sequence of the recombinant or synthetic gelatin-like polypeptide is identical to or essentially similar to a selected region of the amino acid sequence of a native collagen, the selected region having a calculated average glass transition temperature higher than the calculated average glass transition temperature of the complete native collagen by at least 10 degrees Celsius.

25. (Currently amended) A composition as in claim 24 wherein the native collagen sequence is selected from the group consisting of a natural human collagen amino acid sequence[[s]], a non-human collagen amino acid sequence[[s]], a rat collagen amino acid sequence[[s]], a rabbit collagen amino acid sequence[[s]] and a mouse collagen amino acid sequence[[s]].

26. (Currently amended) A composition as in claim 24 wherein the ~~complete recombinant or synthetic gelatin-like polypeptide~~ selected region of the amino acid sequence of the native collagen has a calculated average glass transition temperature higher than the calculated average

glass transition temperature of the complete native collagen by an amount selected from the group consisting of ~~about 10 degrees Celsius~~, about 20 degrees Celsius, about 30 degrees Celsius and about 40 degrees Celsius.

27. (Previously presented) A composition as in claim 24 wherein the recombinant or synthetic gelatin-like polypeptide sequence has a measured glass transition temperature higher than the measured glass transition temperature of the native collagen by an amount selected from the group consisting of about 5 degrees Celsius, about 10 degrees Celsius and about 20 degrees Celsius.

28. (Currently amended) A composition as in claim 24 wherein ~~the native collagen amino acid sequence has a calculated moving average glass transition temperature along the native collagen amino acid sequence with a value for the amino acid region of the native collagen of at least about 10 degrees Celsius higher than the calculated average collagen glass transition temperature of the complete native collagen and wherein, optionally,~~ the native collagen is human collagen.

29. (Cancelled)

30. (Previously presented) A composition as in claim 1 wherein the complete amino acid sequence of the recombinant or synthetic gelatin-like polypeptide comprises a repetitive sequence being a repeated unit sequence, the unit sequence being essentially similar to a region of a native collagen amino acid sequence.

31. (New) A process as in claim 9 comprising selecting a region of the amino acid sequence of a native collagen having a calculated average glass transition temperature higher than the calculated average glass transition temperature of the complete native collagen by at least 10 degrees Celsius and selecting the recombinant or synthetic gelatin-like polypeptide to have an amino acid sequence identical to or essentially similar to the selected region of the native collagen sequence.

32. (New) A process as in claim 31 comprising identifying the amino acid region having a calculated glass transition temperature higher than the calculated average glass transition

temperature of the complete native collagen sequence by calculating a moving average glass transition temperature over a number of amino acids of the native collagen sequence.